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Federal Bar No. CW-2628

Attorneys for Plaintiffs,  
Savient Pharmaceuticals, Inc.,  
(formerly known as Bio-Technology General Corp.),  
Organon (Ireland) Ltd.,  
and Organon USA Inc.

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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

SAVIENT PHARMACEUTICALS, INC.  
(formerly known as  
Bio-Technology General Corp.),  
ORGANON (IRELAND) LTD., and  
ORGANON USA INC.,

Plaintiffs,

v.

DURAMED PHARMACEUTICALS, INC., and  
BARR LABORATORIES, INC.,

Defendants.

Civil Action No. 00-4509-DMC

**FIRST AMENDED  
COMPLAINT**

Plaintiffs Savient Pharmaceuticals Inc. ("Savient") (formerly known as Bio-Technology General Corp.), Organon (Ireland) Ltd. ("Organon Ireland"), and Organon USA Inc. ("Organon

USA"), by way of First Amended Complaint against defendants Duramed Pharmaceuticals, Inc. ("Duramed" and Barr Laboratories, Inc. ("Barr"), by and with leave of Court granted on the record on June 30, 2003, allege and say:

### **THE PARTIES**

1. Plaintiff Savient is a corporation organized under the laws of the State of Delaware, with offices at One Tower Center, East Brunswick, New Jersey 08816.
2. Plaintiff Organon Ireland is an Irish corporation, with offices at Drynam Road, Swords, Dublin, Ireland.
3. Plaintiff Organon USA is a corporation organized under the laws of the State of New Jersey, with offices at 375 Mount Pleasant Avenue, West Orange, New Jersey 07052.
4. Defendant Duramed is a corporation organized under the laws of the State of Delaware, with offices at 6040 Duramed Drive, Cincinnati, Ohio 46213.
5. Defendant Barr is a corporation organized under the laws of the State of New York, with offices at 2 Quaker Road, Pomona, New York 10970.
6. Upon information and belief, Duramed is a wholly owned subsidiary of Barr.

### **JURISDICTION AND VENUE**

7. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*
8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).
9. Venue is proper in this District pursuant to 28 U.S.C. §§1391(c) and 1400(b).

**THE PATENT IN SUIT**

10. U.S. Patent RE35,724 ("the '724 patent") was legally and duly issued on February 3, 1998.

11. Savient has been and continues to be the owner of all right, title, and interest in and to the '724 patent.

12. Organon Ireland is the exclusive licensee of the '724 patent. The '724 patent covers Mircette<sup>®</sup> tablets, which are exclusively marketed by Organon USA (an affiliate of Organon Ireland) in the United States.

**COUNT ONE: INFRINGEMENT AGAINST DURAMED AND BARR**

13. Savient, Organon Ireland, and Organon USA repeat the allegations of paragraphs 1 through 12 as if set forth at length herein.

14. Duramed has filed in the U.S. Food and Drug Administration an Abbreviated New Drug Application ("ANDA"), No. 75-863, for a generic version of Mircette tablets that contained a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (*i.e.*, a "Paragraph IV certification") with respect to U.S. Patent No. 4,921,843, which reissued as the '724 patent.

15. On August 1, 2000, Duramed sent a notice of Paragraph IV certification to Organon USA stating, *inter alia*, that Duramed "seeks to obtain approval to engage in the commercial manufacture and sale of its version of Mircette<sup>™</sup> Tablets prior to the expiration date of October 20, 2008" which is the date of expiration of the '724 patent. Organon USA received Duramed's notice of Paragraph IV certification on or about August 8, 2000.

16. The '724 patent, which covers Mircette tablets, also covers the composition and use of "Kariva," Duramed's generic version of Mircette tablets.

17. Duramed and Barr have and continue to make, use, sell, and offer for sale in the United States and in this judicial district an oral birth control product called "Kariva," their generic version of Mircette tablets.

18. By their aforesaid actions, Duramed and Barr have been and still are infringing the '724 patent, literally and/or under the doctrine of equivalents.

19. The infringement by Duramed and Barr of the '724 patent has been and will be willful, without license, and carried out with the full knowledge of the '724 patent.

#### **PRAAYER FOR RELIEF**

WHEREFORE, plaintiffs Savient, Organon Ireland, and Organon USA respectfully pray that this Court:

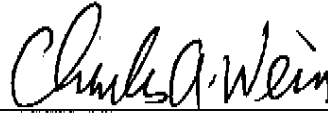
- a. issue an injunction enjoining Duramed and Barr, their officers, agents, servants and employees, and those persons in active concert or participation with any of them from making, using, selling, offering for sale, or importing their generic version of Mircette tablets which is the subject of ANDA No. 75-863, and any other generic version of Mircette tablets, prior to the expiration of the '724 patent;
- b. award Savient, Organon Ireland, and Organon USA damages, enhanced, damages, and attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285;
- c. award Savient, Organon Ireland, and Organon USA an assessment of interest and costs; and

d. award Savient, Organon Ireland, and Organon USA such other and further relief as the Court deems just and proper.

KENYON & KENYON

Attorneys for Plaintiffs,  
Savient Pharmaceuticals, Inc.  
(formerly known as Bio-Technology  
General Corp.),  
Organon (Ireland) Ltd.,  
and Organon USA Inc.

By:



RICHARD L. DELUCIA

CHARLES A. WEISS (CW-2628)

DATED: July 14, 2003

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CERTIFICATE OF SERVICE

AT 8:30 4:30 M  
WILLIAM T. WALSH  
CLERK

I hereby certify that on the date shown below I caused a copy of the foregoing "First Amended Complaint" to be served on counsel for defendants via DHL overnight delivery as follows:

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Charles A. Weiss

DATED: July 14, 2003